UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

	:	**Case No. 1:01-CV-9000**
	:	
IN RE: SULZER HIP PROSTHESIS	:	**(MDL Docket No. 1401)**
AND KNEE PROSTHESIS	:	
LIABILITY LITIGATION	:	**JUDGE O'MALLEY**
	:	
	:	**MEMORANDUM AND ORDER**
	:	

NOTE – A SUMMARY OF THIS ORDER IS SET OUT AT PAGE 29.

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By way of Orders dated August 29, 2001 and August 31, 2001, this Court conditionally certified a national plaintiff settlement class composed, essentially, of "all Americans in whom were implanted a recalled Inter-Op acetabular shell, together with their loved ones." Order at 9 (Aug. 31, 2001) ("Class Order"). The Court also conditionally certified two sub-classes: those persons "who have already had revision surgery, and those who have not had (but yet may have) revision surgery." Id. In the Class Order, the Court also gave preliminary approval to a proposed class action settlement agreement. Id. at 58. Later, by way of Orders dated September 17, 2001 and September 26, 2001, the Court enjoined state court litigation "related in any way to claims arising out of an alleged product defect in Sulzer Orthopedic, Inc.'s Inter-Op acetabular shell hip implant." Order at 2 (Sept. 17, 2001) ("Injunction Order"). The Court also approved the parties' proposed plan for giving initial notice of the pendency of a class action, including

their proposed forms of notice, with certain minor modifications. See Order at 2-3 (Sept. 20, 2001) ("Notice Order").

Before the Court issued the Class Order, the parties had argued it was appropriate to include in the settlement class not only persons in whom were implanted a defective Inter-Op hip implant, but also persons in whom were implanted a defective "Natural Knee II Tibial Baseplate" knee implant, also manufactured by Sulzer. The Court declined, at that time, to include such persons in the conditionally certified class because, among other reasons, the Court believed it did not have jurisdiction to do so. See Class Order at 22-23 (setting out three reasons why "knee claimants" would not be included in the class, the first reason being that "the Court does not currently have jurisdiction over any case involving a knee implant").

Subsequently, the Court did obtain jurisdiction over a case involving an allegedly defective Natural Knee II implant. Specifically, on September 5, 2001, the Federal Judicial Panel on Multi-District Litigation ("MDL Panel") transferred to this Court Harp v. Sulzer Medica Ltd., case no. 01-CV-0183-E(M) (N.D.

Okla 2001), consolidating the Oklahoma case as a part of the Inter-Op Hip Prosthesis Litigation.[1] The MDL transfer order specifically notes that Harp "appears . . . [to] involve questions of fact which are common to the actions previously transferred to [this Court]" as a part of the MDL Proceedings. Given that the Court's jurisdictional objection to including "knee claimants" in the class action no longer existed, plaintiffs' class counsel in this case have filed the following motions: (1) motion to file a second amended class action complaint to include a knee subclass (docket no. 111); (2) motion to amend the Class Order to include knee claimants as part of the class (docket no. 109); (3) motion for approval of an amended class action settlement agreement that includes knee claimants (docket no. 110); and (5) motion to amend the Notice Order to give notice to knee claimants (docket no. 108).

The defendants do not oppose any of these motions; to the contrary, defendants join plaintiffs in the motion to amend the Notice Order, and defendants move to join the plaintiffs in the motion to amend the Class Order (docket no. 112). In addition, defendants move to amend the Injunction Order so that it also explicitly enjoins state-court litigation related to claims arising out of knee implants (docket no. 113).

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[1] The MDL Panel "conditionally transferred Harp to this Court as a part of the MDL proceedings on August 20, 2001; after plaintiff's counsel in Harp did not object to transfer and consolidation of the case, the transfer became final on September 5, 2001. Separately, this Court has jurisdiction over Mazzolini v. Sulzer Orthopedics, Inc., case no. 01-CV-2147 (N.D. Ohio 2001), which was filed in this district. In Mazzolini, plaintiff Vincent Mazzolini alleges he received a defective Natural Knee II implant, and he seeks to represent a class of similarly situated persons. The Mazzolini case has not been transferred and consolidated with the Inter-Op Hip Prosthesis Litigation through the MDL Panel because it does not need to be – "[p]otential 'tag-along actions' filed in [this district court] require no action on the part of the Panel and requests for assignment of such actions to the Section 1407 transferee judge should be made in accordance with local rules for the assignment of related actions." 28 U.S.C. §1407, Rule 7.5(a). Mazzolini was originally assigned to the Honorable Leslie Brooks Wells, and plaintiffs moved to transfer this case to the undersigned "pursuant to Rule 7.5(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Rule 42(a) of the Federal Rules of Civil Procedure, and Rule 3.1(b)(3) of the Local Rules of the Northern District of Ohio." Motion at 1. This motion was granted on September 17, 2001.

On October 17, 2001, the Court held a hearing on all seven of these motions. For the reasons stated below, all of these motions **except** the defendants' motion to amend the Injunction Order (docket no. 113) are **GRANTED**. The Court will rule on this last motion in a separate Order, following receipt of additional briefing.

I. Background.

The Court has set out the background of this multi-district, national class action litigation a number of times before, in the context of discussing the Inter-Op hip implants. See Class Order at 1-7; Injunction Order at 2-5. The factual background is virtually identical in the context of the Natural Knee II implants, as well. Thus, the Court simply adds here certain facts pertinent to knee claimants, and incorporates by reference the background discussion it set out in its earlier Orders.[2]

Defendant Sulzer Orthopedics "is a designer, manufacturer and distributor of orthopedic implants for hips, knees, shoulders, and elbows," including both the Inter-Op hip implant and the Natural Knee II implant. Class Order at 1. At about the same time that Sulzer Orthopedics learned it may have defectively manufactured a number of Inter-Op hip implants, it learned it may have also defectively manufactured a number of Natural Knee II implants. The suspected manufacturing defect in both types of implants was

[2] In the Class Order, the Court addressed the question of whether knee claimants should be included in the conditionally certified settlement class and noted that it "was presented with virtually no factual development regarding the reason the knee implants are allegedly defective, the effect of the alleged defect, the type and level of damages suffered by persons who received knee implants, and so on. Without this factual development, the Court cannot assess adequacy, typicality, commonality, or even numerosity, as those requirements apply to knee implant claimants in particular, either as a subclass or as included within a larger 'hip and knee implant' class." Class Order at 22 n.18. As is made clear below, the parties' pending motions cure the problem of lack of factual development.

the same – the remainder on the implant of a slight residue of lubricant used during the manufacturing process, which worked to prevent the implant from bonding with the natural bone.[3]

Just as it did with the Inter-Op hip implants, Sulzer Orthopedics voluntarily notified the public that a problem existed with certain Natural Knee II implants. Specifically, on May 17, 2001 – about five months after it had announced the voluntary recall of certain Inter-Op hip implants – Sulzer Orthopedics sent a "Special Notification Letter" to surgeons who had implanted certain identified "Natural Knee II Porous-Coated Stemmed Tibia1 Baseplates."[4] The purpose of this Notification was to make the surgeons aware of "unanticipated adverse clinical outcomes" associated with these baseplates – specifically, "aseptic loosenings," similar in nature to what had occurred with the Inter-Op acetabular shell hip implants. In addition to issuing this Notification, Sulzer Orthopedics also asked its distributors and sales agents to return any Natural Knee II tibial baseplates manufactured from July 2000 to December 2000 that had not already been implanted.

The manufacturing defect occurred during production of about 1,600 Natural Knee II tibial baseplates, about 1,336 of which were implanted in patients. As of October 11, 2001, approximately 440 revision surgeries for the Natural Knee II implants had taken place. The Sulzer defendants predict there will be eventually be a total of between 550-600 knee revision surgeries.

Just as did persons who received defective Sulzer hip implants, persons with defective Sulzer knee

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[3] There remains some question whether critical steps of the knee implant and hip implant manufacturing processes were entirely the same, but the alleged defect – that the manufacturing process(es) left a residue of lubricant on the implant – is the same.

[4] The "tibia1 baseplate" is one of four primary parts used for a total knee replacement. In addition to the "tibia1 baseplate," a total knee replacement system is comprised of a femoral component, a patella component, and a tibia baseplate insert.

implants filed lawsuits around the country in both state and federal court. Specifically, various plaintiffs have filed claims related to defective knee implants in 27 state court actions and 5 federal actions; three of these 32 lawsuits (including Mazzolini v. Sulzer Orthopedics, Inc., case no. 01-CV-2147 (N.D. Ohio 2001)) are putative class actions. And, just as in the hip implant lawsuits, the defendants named in these knee implant lawsuits include not only Sulzer Orthopedics, but also: (1) Sulzer Medica USA Holding Company ("Sulzer Medica USA"), a holding company that owns Sulzer Orthopedics; (2) Sulzer Medica Ltd., a Swiss holding company that owns Sulzer Medica USA;[5] (3) Sulzer AG, a Swiss company that previously owned a majority of the stock of Sulzer Medica Ltd.; (4) various other Sulzer-related entities; and (5) various surgeons, hospitals, and medical supply companies connected to the distribution or implantation of the defective product. The causes of action in these lawsuits include claims for defective design, marketing and manufacture; breach of express and implied warranties; negligence; strict liability; and other legal theories of recovery. Furthermore, the nature of the damages alleged by knee claimants and hip claimants is essentially the same. As noted above, pursuant to 28 U.S.C. §1407, the MDL Panel has transferred at least one of these "knee implant cases" to this Court as a part of the MDL proceedings.

II. The Nature and Context of the Issues Presented.

Because "the nature and context of the issues presented" by the pending motions are so important, the Court repeats here several paragraphs contained in its Class Order. See Class Order at 7-8.

Neither the Court's analysis nor the effect of its rulings can be understood without consideration

[5] Sulzer Medica Ltd. is a publicly traded company, its stock listed on the New York Stock Exchange (symbol: SM).

of the context in which both occurred. The parties have jointly approached the Court, seeking only conditional certification of this matter as a class action and preliminary approval of their proposed settlement. As the parties understand, their motion for approval of the proposed settlement agreement, if granted, is only the first step in an extensive and searching judicial process, which may or may not result in final approval of a settlement in this matter.

As the Manual on Complex Litigation indicates, this threshold inquiry often involves no more than an informal presentation of the parties' proposals to the Court. Manual for Complex Litigation, §30.41, at 236 (3rd ed. 1995) ("in some cases this initial [fairness] evaluation can be made on the basis of . . . informal presentations by the settling parties"). This is true because the Court's conditional certification and preliminary approval: (1) triggers a mechanism for more formal notice to all potential class members; (2) determines whether opt-out rights are to be afforded putative class members; (3) defines the scope of discovery to be conducted from that point forward – that is, focuses discovery on the fairness and adequacy of the proposed settlement to the class, as well as on any issues which might call into question the propriety of final certification of the matter as a class action; (4) sets in motion those judicial processes that will culminate in a detailed, full, and final fairness hearing (at which time the question of fairness is reviewed de novo); and (5) establishes procedures for class members to register with the Court objections to or support for the proposed settlement.

Thus, while it is certainly not the role of this Court to simply "rubber-stamp" a motion for conditional certification or preliminary approval (or, for that matter, any motion), the Court also must be mindful of the substantial judicial processes that remain to test the assumptions and representations upon which the parties' motions are premised. The Court reserves for another time the right and obligation to

test all of the premises behind the parties' motions and the Court's ruling, through the most probing of inquiries.[6]

It is also important to note that the pending motions seek incremental amendments to Orders the Court has already issued. For example, the plaintiffs are not seeking initial class certification – the Court has already conditionally certified a settlement class. Rather, the plaintiffs are seeking to expand the class to include another subclass. Thus, virtually all of the legal analysis this Court set out in its earlier Orders is equally apposite to the pending motions. As such, the Court's analysis below incorporates its earlier analyses, and begins where its earlier Orders ended.

III. Class Certification.

A. Rule 23(a).

In its Class Order, the Court described the plaintiffs' position as follows: "In plain English, the plaintiffs propose that the class be made up of all Americans in whom were implanted a recalled Inter-Op acetabular shell, together with their loved ones. This class would then be divided into two sub-classes: [1] those who have already had revision surgery, and [2] those who have not had (but yet may have) revision

[6] Notably, when the Court first considered plaintiffs' motions to conditionally certify a class and preliminarily approve the proposed settlement agreement in August of 2001, the Court allowed counsel from around the country (including counsel representing persons not parties to any federal proceeding) to appear and object. See Class Order at 6 (detailing this procedure); id. at 19-20 (discussing some of the objections). At the October 17, 2001 hearing on the motions seeking to modify the class definition and settlement agreement, some of the same counsel appeared and again objected. Specifically, attorney Edward Blizzard (who represents numerous hip and knee claimants in state court) appeared and, by reference, raised again all of the objections that the objectors had raised in August. The Court has made a point of reviewing and carefully considering all of the written objections again, in light of the pending motions.

surgery." Class Order at 9.

To use plain English again, the plaintiffs now propose that the class also include knee claimants; that is, the class should be made up of all Americans in whom were implanted a recalled Inter-Op acetabular shell or a recalled Natural Knee II tibial baseplate, together with their loved ones. Like the hip claimants, the knee claimants would be divided into two subclasses: (1) those who received knee implants and have already had revision surgery, and (2) those who received knee implants who have not had (but yet may have) revision surgery. Put differently, the plaintiffs propose a class that would include persons who received a defective hip or knee implant, divided into four subclasses.

As before, the Court looks to Rule 23(a) to determine the propriety of conditionally certifying the proposed class. Rule 23(a) "states four threshold requirements applicable to all class actions," including actions involving proposed certifications of a "settlement-only" class. Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 613 (1997). These threshold requirements are:

> (1) numerosity (a "class [so large] that joinder of all members is impracticable"); (2) commonality ("questions of law or fact common to the class"); (3) typicality (named parties' claims or defenses "are typical . . . of the class"); and (4) adequacy of representation (representatives "will fairly and adequately protect the interests of the class").

Id. (quoting Fed. R. Civ. P. 23(a)(1-4)). "Subsection (a) of Rule 23 contains four prerequisites which must all be met before a class can be certified. Once those conditions are satisfied, the party seeking certification must also demonstrate that it falls within at least one of the subcategories of Rule 23(b)." In re American Medical Systems, Inc., 75 F.3d 1069, 1079 (6th Cir. 1996) (hereinafter, "AMS").

1. Numerosity.

The Court earlier found that "the proposed class is so large that joinder of all members is impracticable." Class Order at 11. The new proposed class is even larger. Accordingly, the Court comes to the same conclusion as it did before – plaintiffs have met the numerosity requirement.

2. Commonality.

The commonality requirement states that there must be "questions of law or fact common to the class." The commonality test "is qualitative rather than quantitative, that is, there need be only a single issue common to all members of the class." AMS, 75 F.3d at 1080 (quoting 1 Herbert B. Newberg & Alba Conte, Newberg on Class Actions, §3.10, at 3-47 (3rd ed. 1992)). If questions of law or fact common to all of the class members are far outweighed by differences, however, then class certification is inappropriate. "[W]here the defendant's liability can be determined on a class-wide basis because the cause of the disaster is a single course of conduct which is identical for each of the plaintiffs, a class action may be the best suited vehicle to resolve such a controversy." Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1197 (6th Cir. 1988).

In its original Class Order, the Court identified a number of "questions of law or fact common to all members of the class." Class Order at 13. These included whether the hip implants had a defect, "whether the defendants adequately tested the safety of their product, when the defendants learned of the defect, . . . whether they timely took action upon learning the defect might exist," and also "the relationships between the various 'Sulzer-related' corporate entities." Id. These questions all apply equally to the Natural Knee II implants, especially because the hip implant defect and knee implant defect are the same. Indeed, yet another question of law and fact common to all members of the class, including both knee and

hip implant recipients, now appears ascendent – the question of what insurance policies apply, and to what extent persons who received these implants may recover under each policy.[7]

Thus, the Court again concludes that the questions of fact and law that are common to the members of the newly proposed "hip and knee implant class" are substantial, and are not outweighed by questions of fact and law idiosyncratic to each plaintiff. Accordingly, the Court concludes that the plaintiffs have carried their burden of showing that the proposed settlement class meets the requirement of Rule 23(a)(2).[8]

3. Typicality.

The typicality requirement is meant to ensure that the named parties' claims are typical of the claims advanced by the entire class. A plaintiff's claim is typical "if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory." AMS, 75 F.3d at 1081 (quoting 1 Newberg, supra, § 3-13, at 3-76 (footnote

[7] Put simply, there are two groups of insurance policies that may supply coverage to persons who received the defective hip and knee implants; it is currently unsettled whether the second group of policies provides any coverage, and whether the first group of policies provides coverage to hip claimants only, or to both knee and hip claimants. These questions, which are of paramount importance in the context of a settlement class, apply equally to both knee and hip claimants. Indeed, there is a serious danger in not settling these questions in the context of a class action including both hip and knee claimants. This issue is discussed more fully below, in section IV.A of this Order.

[8] At the motion hearing, attorney Edward Blizzard objected to expansion of the class to include knee claimants, focusing on the issue of commonality and arguing that the questions presented by knee claimants and hip claimants do not share sufficient legal or factual bases. This argument is somewhat undercut by Mr. Blizzard's own use, in Texas state court, of Texas Rule of Civil Procedure 40 – Mr. Blizzard joined knee claimants with hip claimants in his consolidated state court action on the basis that the knee claims and hip claims arose out of the "same transaction, occurrence, or series of transactions or occurrences and [that] question[s] of law or fact common to them will arise in the action." Tex. R. Civ. P. 40. In any event, the Court disagrees with Mr. Blizzard, concluding that the knee claimants and hip claimants easily meet the commonality requirement of Rule 23(a)(2).

omitted)). The typicality requirement ensures that the representative plaintiffs' interests are aligned with those of the proposed class, and in pursuing their own claims, the named plaintiffs will also advance the interests of the class members. Id. "Sometimes the issues are plain enough from the pleadings to determine whether the interests of the absent parties are fairly encompassed within the named plaintiff's claim, and sometimes it may be necessary for the court to probe behind the pleadings before coming to rest on the certification question." General Telephone Co. of Southwest v. Falcon, 457 U.S. 147, 160 (1982).

In the Court's Class Order, it identified the five named representative plaintiffs in the first amended complaint, and concluded that these five plaintiffs fairly represented the hip class and the hip subclasses. In the plaintiffs' proposed second amended class action complaint, the plaintiffs have added four more representative plaintiffs: Robert and Stephanie Reschke, and Vincent and Vivian Mazzolini. Robert Reschke was implanted with a recalled Natural Knee II implant and, on August 5, 2001, underwent revision surgery to correct problems he was experiencing with the implant. Vincent Mazzolini was implanted with a recalled Natural Knee II implant, but has not undergone a revision surgery.

Thus, based on these additional allegations, the Reschkes and Mazzolinis appear to have claims common to the proposed additional subclasses of plaintiffs, in the same way as the original five representative plaintiffs appear to have claims common to the two original subclasses of plaintiffs. See Class Order at 15-16. Simply, the Court concludes that amended complaint itself, viewed in light of the history of this case, shows that the nine representative plaintiffs' interests are aligned with those of the proposed class and subclasses, and in pursuing their own claims, the named plaintiffs will also advance the interests of the class members and the members of each subclass. As such, the plaintiffs have carried their burden of showing that the proposed class meets the commonality requirement of Rule 23(a)(3).

4. Adequacy.

The adequacy requirement ensures that the named representative plaintiffs "will fairly and adequately represent the interests of the class." Fed. R. Civ. P. 23(a)(4). Essentially, the adequacy requirement is meant to test "the experience and ability of counsel for the plaintiffs and whether there is any antagonism between the interests of the plaintiffs and other members of the class they seek to represent." Cross v. National Trust Life Ins. Co., 553 F.2d 1026, 1031 (6th Cir. 1977).

The Court earlier concluded that "[t]here does not appear to be any serious question of inadequacy in this case." Class Order at 18. This circumstance has not changed. Furthermore, plaintiffs have continued to maintain "structural assurance of fair and adequate representation for the diverse groups and individuals affected," by dividing the now-larger proposed class into homogeneous subclasses and providing each subclass with its own counsel. Amchem, 521 U.S. at 627. Specifically, the plaintiffs have provided for separate subclass representation as follows:

Subclass	Representative Primary & Derivative Plaintiffs	Subclass Counsel
1 – **hip** claimants who have had revision	George & Mary Jean Yasenchak	R. Eric Kennedy
2 – **hip** claimants who have **not** had revision	Harlan & Brenda Herman, and Linda Wells	Richard S. Wayne
3– **knee** claimants who have had revision	Robert & Stephanie Reschke	Peter J. Broadhead
4 – **knee** claimants who have **not** had revision	Vincent & Vivian Mazzolini	Phillip A. Ciano

Thus, to the extent there exists any "antagonism" between the interests of the named plaintiffs amongst each other, and as against other class members, the plaintiffs have cured this conflict by the use of separately represented subclasses. Accordingly, the Court concludes that the plaintiffs have carried their burden of showing that the named representative plaintiffs will fairly and adequately represent the interests of the class in this case.

B. Rule 23(b).

Not only must the "four prerequisites [of Rule 23(a)] . . . all be met before a class can be certified," "the party seeking certification must also demonstrate that it falls within at least one of the subcategories of Rule 23(b)." AMS, 75 F.3d 1079 (emphasis in original). The Court earlier concluded that "certification of this litigation as a class action under Rule 23(b)(3) is appropriate because the questions of law or fact common to the members of the class do predominate over any questions affecting only individual members, and because a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Class Order at 30. The entirety of the Court's reasoning supporting this conclusion applies equally to a class including both hip claimants and knee claimants. Id. at 23-30.[9] The Court also earlier concluded that "the injunctive relief requested by the class is more than merely tangential and is an

[9] For example the Court noted, in its Class Order, that "[i]t appears that a single set of operative facts establishes liability in this case – the Court has read many of the complaints transferred here by the MDL Panel, and the plaintiffs repeatedly recite identical allegations, with no substantial factual additions or differences, to support their claims. Furthermore, it appears a single proximate cause applies to each potential class member and defendant – that is, Sulzer Orthopedics' manufacture and sale of Inter-Op shell implants with, as it has admitted, 'a trace of lubricant residue [left] on the surface.'" Class Order at 24. This statement remains entirely true even with inclusion of the knee claimants in the settlement class.

appropriate element of the redress awarded to the class as a whole. Accordingly, the Court concludes that certification of this

litigation as a settlement class action under Rule 23(b)(2) is also appropriate." Id. at 31. Again, the entirety of the Court's reasoning supporting this conclusion applies equally to a class including both hip claimants and knee claimants. Id. at 30-31. Thus, conditional certification of a settlement class including knee claimants is appropriate.

C. Knee Claimant Treatment in the Earlier Class Order.

Given that the Court initially declined to include knee claimants in the conditionally certified class, it is appropriate to explain here what has changed.

When the Court first addressed the propriety of including knee claimants in the conditionally certified class, it gave three reasons for concluding that it was not appropriate to include knee claimants. Class Order at 22-23. The first reason was lack of jurisdiction. As explained above, this hurdle has been overcome by virtue of this Court's having obtained jurisdiction over Harp and Mazzolini.

Second, the Court had "serious questions regarding whether the persons bringing 'knee implant cases:' (1) sufficiently share questions of law or fact in common with the hip implant cases, (2) state claims that are 'typical' of those made by the 'hip implant class,' or (3) would be adequately represented by the 'hip implant' class counsel." Class Order at 22. For example, the Court noted, "[a]t the very least, it appears that 'knee implant' plaintiffs would need their own subclass counsel." Id.

A large part of the reason that the Court had these "serious questions" was because, at that juncture, the parties had "presented [the Court] with virtually no factual development regarding the reason

the knee implants are allegedly defective, the effect of the alleged defect, the type and level of damages suffered by persons who received knee implants, and so on." Id. at 22 n.18. Since then, of course, the parties have provided factual development regarding the Natural Knee II implants, which is set out above. And, as discussed, these facts reveal that, in fact, knee claimants have claims that are largely identical, factually and legally, to the claims of hip claimants. Furthermore, the knee claimants do, in fact, have their own subclass counsel. Thus, the first two reasons the Court had to exclude knee claimants from the settlement class have become moot.

The third reason, however, has not become moot. The Court explained its third reason for not including knee claimants in the settlement class as follows:

> the defendants' identification of knee implants as problematic on May 15, 2001 – and not within the April 2000 / April 2001 time period – suggests that claims related to knee implants may be covered by a different insurance policy. If there exist insurance funds available to pay for knee implant claims additional to and different from insurance funds to pay for hip implant claims, then inclusion of the knee implant claimants in the settlement class, pursuant to the **existing** provisions contained in the settlement agreement, is inappropriate.

Class Order at 22-23 (bold emphasis added). In fact, the parties are vigorously pursuing discovery to determine whether additional insurance policies are available to pay knee claims and/or hip claims.

Rather than revisiting this third reason here, however, the Court addresses this issue below in the context of assessing the fairness of the proposed settlement agreement. It is sufficient to state here that the parties have recognized, in their most recent version of the proposed settlement agreement, that knee claimants and hip claimants may be entitled to different insurance proceeds, so the parties have changed the provisions of the agreement to reflect this circumstance. The possible existence of different insurance proceeds for knee and hip claimants may argue for subclass treatment, but does not argue for complete

exclusion from the class of knee claimants. To the contrary, the common interest of knee claimants and hip claimants in securing all available insurance proceeds, and ensuring those proceeds are properly allocated, suggests that a class including both hip claimants and knee claimants is apt. In any event, the Court addresses this third concern below, in the context of assessing the fairness of the proposed settlement agreement, rather than in the context of assessing whether knee claimants should be included in the settlement class under Rule 23(a).

D. Class Definition.

Having concluded that it is appropriate to amend the Class Order to include knee claimants, the Court conditionally certifies the following class:

> All citizens or residents of the United States who have had Affected Inter-Op acetabular shell hip implants or Affected Natural Knee II tibia1 baseplate implants placed in their bodies, together with their associated consortium claimants.[10] Further, this class shall be divided into four subclasses, as follows: Subclass 1 shall consist of those class members who received Affected Inter-Op hip implants and who undergo revision surgery to correct problems with those implants prior to the Final Judicial Approval Date, and their associated consortium claimants. Subclass 2 shall consist of class members who received Affected Inter-Op hip implants and may need to undergo revision surgery to correct problems with those implants after the Final Judicial Approval Date, and their associated consortium claimants. Subclass 3 shall consist of those class members who received Affected Natural Knee II baseplate implants and who undergo revision surgery to correct problems with those implants prior to the Final Judicial Approval Date, and their associated consortium claimants. Subclass 4 shall consist of class members who received Affected Natural Knee II baseplate implants and may need to undergo revision surgery to correct problems with those implants after the Final Judicial Approval Date, and their

[10] The "Affected Inter-Op acetabular shell hip implants" and "Affected Natural Knee II tibia1 baseplate implants" will be identified with particularity by the parties to the proposed settlement agreement.

associated consortium claimants.[11]

Notably, this class definition is worded differently than the plaintiffs' proposed class definition. See memo. in support of motion to amend Class Order at 3-4. The essence of the proposed class definition and the Court's class definition, however, is precisely the same. The reason the Court did not adopt the proposed definition is that it is very lengthy, contains nine footnotes, and refers to numbered provisions of the proposed settlement agreement that may change. The Court believes the definition it uses here will allow class members to more easily understand that they do, in fact, belong to the class. The Court's definition does not prevent the parties from using a more precise and detailed definition of the settlement class and subclasses in their proposed settlement agreement.[12]

Finally, so that the caption of the case reflects the amended class definition, the caption of this case is hereby changed to "In Re: Sulzer Hip Prosthesis and Knee Prosthesis Liability Litigation."

IV. Fairness of the Proposed Settlement Agreement.

In its earlier Class Order, the Court applied Fed. R. Civ. P. 23(e) and granted preliminary approval to the parties' proposed settlement agreement. Class Order at 31-51. The parties have submitted a

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[11] In this context, the term "Final Judicial Approval Date" means the date (if any) on which this Court's approval of the proposed settlement agreement becomes final by the exhaustion of all appeals.

[12] For example, the Court uses the term "associated consortium claimants," while the proposed settlement agreement refers to "associated Derivative Claimants and Representative Claimants," which terms are carefully and appropriately defined. Given that the class settlement agreement is necessarily more detailed than the Court's conditional class certification, this circumstance is to be expected.

revised proposed settlement agreement ("Fourth Settlement Agreement"),[13] taking into account the inclusion in the settlement class of knee claimants. Nearly all of the broad outlines, and also the vast majority of the specific provisions, of this new agreement are unchanged. Thus, the Court examines here only those aspects of the Fourth Settlement Agreement that have been substantially modified.

Notably, the Court applies the same standards and analysis here as it did in the Class Order. In its earlier Class Order, the Court spent nearly 20 pages explaining the appropriate standards for assessing the fairness of a proposed settlement agreement under Fed. R. Civ. P. 23(e), and applying those standards to preliminarily conclude the parties' agreement was fair. Class Order at 31-50. The length of this analysis highlights the importance this Court gives to ensuring that the parties in this case reach a resolution that is "fair, adequate, and reasonable, as well as consistent with the public interest." United States v. Jones & Laughlin Steel Corp., 804 F.2d 348, 351 (6th Cir. 1986); Williams v. Vukovich, 720 F.2d 909, 921 (6th Cir. 1983). By not repeating here the bulk of the analysis set out in the Class Order, the Court does not mean to remotely suggest otherwise. There is no good reason, however, to repeat, for example, the discussion of how the proposed revised settlement agreement treats subrogation interests, see Class Order at 47-48, given that the revised agreement is identical to the prior agreement in this respect.

It does bear repeating, however, that the parties currently seek only preliminary approval of the class settlement agreement. In making a preliminary assessment of the fairness of the proposed settlement

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[13] The parties have now submitted four versions of the proposed settlement agreement: (1) the original version, or "First Settlement Agreement," dated August 15, 2001; (2) the "Second Settlement Agreement," amended and restated August 23, 2001; (3) the "Third Settlement Agreement," amended and restated September 12, 2001; and (4) the "Fourth Settlement Agreement," amended and restated October 12, 2001. The Court expects that, as negotiations continue and the parties' agreement is solidified and refined, the parties will file additional versions of the proposed settlement agreement.

agreement, the Court's "intrusion upon what is otherwise a private consensual agreement negotiated between the parties to a lawsuit must be limited to the extent necessary to reach a reasoned judgment that the agreement is not the product of fraud or overreaching by, or collusion between, the negotiating parties, and that the settlement, taken as a whole, is fair, reasonable and adequate to all concerned." Officers for Justice v. Civil Serv. Comm'n of the City and County of San Francisco, 688 F.2d 615, 625 (9th Cir. 1982), cert. denied, 459 U.S. 1217 (1983). A preliminary fairness assessment "is not to be turned into a trial or rehearsal for trial on the merits," for "it is the very uncertainty of outcome in litigation and avoidance of wasteful and expensive litigation that induce consensual settlements." Id. Rather, the Court's duty is to conduct a threshold examination the overall fairness and adequacy of the settlement in light of the likely outcome and the cost of continued litigation. Ohio Public Interest Campaign v. Fisher Foods, Inc., 546 F. Supp. 1, 7 (N.D. Ohio 1982).

A. The New Terms in the Fourth Settlement Agreement.

The Fourth Settlement Agreement is different from the Third Settlement Agreement, which the Court earlier preliminarily approved, in two principle areas. First, the Fourth Settlement Agreement includes a provision discussing a "Guaranteed Payment Option," or "GPO." Fourth Settlement Agreement at Art. 14. The GPO provision remains somewhat vague because the parties have not yet agreed on all of the terms related to the GPO, but the gist of this provision is that class members can elect to receive "the same benefits provided for hereunder on an accelerated schedule," and that these benefits "would be paid even if the Settlement Agreement does not receive Trial Court Approval or Final Judicial Approval or is otherwise terminated for any reason." Id. In other words, the GPO would allow any class member to elect

to receive the benefits proposed under the settlement agreement, even if the agreement is not finalized, and to receive them quickly. The inclusion of this GPO provision in the Fourth Settlement Agreement does not change the Court's preliminary conclusion that the agreement is fair; if anything, the GPO provision bolsters the Court's conclusion.

The second principal change is that the Fourth Settlement Agreement includes knee claimants, and proposes a two-step method of payment to knee claimants to settle their claims. Step one is to simply treat the knee claimants in exactly the same way as the hip claimants. Thus, knee claimants, like hip claimants, would receive the benefits of the research fund and medical monitoring fund. Knee claimants would also receive the same compensation as hip claimants: to knee claimants who do not have revision surgery, a guaranteed fixed payment of $750 in cash, $2,000 in stock, and $500 to their spouses; to knee claimants who have one revision surgery, a guaranteed fixed payment of $37,500 in cash, $20,000 in stock, and $5,000 to their spouses; and to knee claimants who have more than one revision surgery, a guaranteed fixed payment of $63,500 in cash, $34,000 in stock, and $5,000 to their spouses. Knee claimants would also receive payments for attorney fees, subrogated medical expenses, any medical expenses associated with revision surgery, and so on. And, like the hip claimants, the knee claimants are eligible to receive additional compensation for "extraordinary injuries," to be paid out of the Extraordinary Injury Fund.

Given that inclusion of knee claimants in the Fourth Settlement Agreement will increase the amount of guaranteed fixed compensatory payments, two questions arise: (1) where is the money coming from to

make these additional payments? and (2) will there end up being less money available for hip claimants?[14]

The answer to the first question is that the money for the additional guaranteed fixed compensatory payments to knee claimants will come out of the Extraordinary Injury Fund. Essentially, the Fourth Settlement Agreement modifies the Third Settlement Agreement by promising a greater amount of guaranteed fixed payments to the larger class, paid for by offering a smaller total amount of compensation for extraordinary injuries. At first, the Court was concerned that this reallocation would leave the Extraordinary Injury Fund so small that it would not provide meaningful compensation to claimants with extraordinary injuries. At the motion hearing, however, the parties assured the Court that, even under the terms of the Fourth Settlement Agreement, the Extraordinary Injury Fund will contain a minimum of $30 million, and possibly much more. The Court is preliminarily satisfied, at this juncture, that the Extraordinary

[14] Inclusion of knee claimants in the class settlement agreement would also increase the amount of payments for attorney fees, revisions surgery, subrogated medical payments, and so on. Because the "payment streams" for all of these amounts to knee claimants are the same as the payment stream for the guaranteed fixed compensatory payments, the Court discusses only the latter, to simplify the analysis.

Injury Fund remains a fair and meaningful source of compensation to claimants with excessive injuries.[15]

The answer to the second question – Will there end up being less money available for hip claimants? – is "maybe, but there ultimately may also be more available to all claimants." The Fourth Settlement Agreement notes that there are two groups of insurance policies that may be available to pay claims, referred to as the "Initial Insurance Policies" (providing about $225 million of coverage) and the "Second Year Insurance Policies" (providing about $165 million of coverage). Fourth Settlement Agreement at 4, 7. The parties currently believe that the hip claimants are entitled to coverage only under the Initial Insurance Policies. The parties further believe that the knee claimants are entitled to coverage under **either** the Initial Insurance Policies **or** the Second Year Insurance Policies, but it is not yet clear which policies apply.

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[15] In its earlier Class Order, the Court made the following observations regarding the Extraordinary Injury Fund, which remain apt:

> The Court's final determination of the fairness of the settlement will depend in large part upon the parties' ability to craft a fair and equitable scheme for awarding "matrix compensation benefits," and the amount of money available to pay them. A full description of these benefits, and of those qualified to receive them, will need to be determined, moreover, prior to any opt-out notices are sent to class members; in the absence of such information, no informed opt-out decision could be made.
>
> At this juncture, however, the Court concludes preliminarily that the fairness of this scheme is supported by: (1) the fact that the parties have provided for some mechanism to process individual claims; (2) the parties' tentative identification of appropriate factors to include in the matrix; (3) the apparent fairness of the tentative claims administration mechanism, which is designed to include an independent administrator and "appeal rights;" and (4) the apparent likelihood that the amount of money in the Extraordinary Injury Fund will be substantially more than $30 million. Thus, while the Court retains real concerns regarding the sufficiency of the total funds contained in, and the details of administration of, the Extraordinary Injury Fund, the Court concludes preliminarily that the fairness of the procedure for processing individual claims is within the range of reasonableness.

Class Order at 46-47.

Obviously, the plaintiffs hope to prove the knee claimants are covered under the Second Year Insurance Policies, as this would mean a greater total of insurance funds available to pay claims, and plaintiffs' counsel are vigorously pursing all available coverage. If the plaintiffs fail to obtain a judgment (or settlement) allowing them to receive coverage under the Second Year Insurance Policies, then the answer to the second question is "yes" – there will end up being less money available for hip claimants under the Fourth Settlement Agreement than was contemplated under the Third Settlement Agreement, because some of the total is now being paid to knee claimants. If, on the other hand, the plaintiffs succeed in obtaining a judgment (or settlement) allowing them to receive coverage under the Second Year Insurance Policies, then the answer to the second question is "no" – because the Fourth Settlement Agreement provides, in essence, that the knee claimants will "pay back" the funds they "took" from the hip claimants.[16] There also remains some possibility, as yet undeveloped, that all claimants may be entitled to receive insurance proceeds from both policy groups. If that occurs, the total available to hip claimants may increase.

This last provision, contained in Article 11 of the Fourth Settlement Agreement, is the second of the two-step method of payment to knee claimants to settle their claims. Article 11 provides that, if the plaintiffs succeed in obtaining funds from the Second Year Insurance Policies, then any payments made to knee claimants that reduced the Extraordinary Injury Fund for hip claimants will be reimbursed from the Second Year Insurance Policy proceeds. Further, the knee claimants would then have their own Extraordinary Injury Fund, which would be funded by the Second Year Insurance Policies. The end result of Article 11 is that, if coverage is available under the Second Year Insurance Policies: (1) hip claimants

[16] This would include repayment of all funds expended from Initial Insurance Policy proceeds to defend knee claims.

would not receive any less than contemplated under the Third Settlement Agreement, even though knee claimants are included in the class; (2) knee claimants would receive payments funded only by the Second Year Insurance Policies, and not the Initial Insurance Policies; and (3) all of the remaining proceeds from the Second Year Insurance Policies would go to the knee claimants (which, ultimately, would likely yield a greater per capita payment to knee claimants than to hip claimants).

At the motion hearing, the Court asked why the hip claimants would agree to a possible diminution in "their share." Put differently, why would subclass counsel for hip claimants agree to these new terms in the Fourth Settlement Agreement, when it seems to provide benefits only to knee claimants? The answer to this question is that hip claimants do obtain some benefit from allowing knee claimants to share in Initial Insurance Policy proceeds, with the possibility of reimbursement – that benefit being the knowledge that the knee claimants will not render the settlement meaningless. As hip subclass counsel points out, if the knee claimants are not included in the settlement, they are sure to seek coverage under the Initial Insurance Proceeds through a separate class action lawsuit (or separate individual lawsuits). This, in turn, would assuredly prevent the insurers from promptly releasing the insurance proceeds to anyone, be they hip claimants or knee claimants, and prompt payment is especially important to hip claimants (whose average age is over 60). Furthermore, as all counsel point out, inclusion of knee claimants in the class and the settlement was their goal from the start. See First Settlement Agreement at §1.1(d, e) (including knee claimants).

The point of this discussion is that the Court is satisfied that subclass counsel were doing their jobs to ensure fulfillment of the "structural assurance of fair and adequate representation for the diverse groups and individuals affected." Amchem, 521 U.S. at 627. As with the Third Settlement Agreement, the

Court's preliminary determination that the Fourth Settlement Agreement is fair is nothing more than "an amalgam of delicate balancing, gross approximations and rough justice." Officers for Justice v. Civil Serv. Comm'n of the City and County of San Francisco, 688 F.2d 615, 625 (9th Cir. 1982), cert. denied, 459 U.S. 1217 (1983) (citations omitted). Virtually all of the factors that this Court examined earlier,[17] and preliminarily found weigh in favor of a conclusion that the proposed settlement agreement is fair, still weigh in favor of that conclusion – which is unsurprising, given that the vast majority of the terms of the Fourth Settlement Agreement are unchanged from the Third Settlement Agreement. At the motion hearing, the Court focused on the primary change to the parties' proposed settlement agreement – inclusion of knee claimants in the class – and the Court preliminarily concludes that the Fourth Settlement Agreement remains fair, adequate, reasonable, and consistent with the public interest. Put differently, the Court does not see any substantial "grounds to doubt its fairness," or see "other obvious deficiencies, such as unduly preferential treatment to class representatives or of segments of the class, or excessive compensation for attorneys," and the proposed settlement "appears to fall within the range of possible approval." Manual

[17] Those factors include: (1) the ability of defendants to withstand a greater judgment; (2) the availability of opt-out rights; (3) the fairness of the procedure for processing individual claims; (4) the treatment of subrogation interests; (5) the likelihood of prompt recovery; (6) a comparison of the recovery the class and subclasses will likely receive pursuant to the settlement agreement to the total recoveries that actually might be received (and collected) by claimants acting individually; (7) the complexity, expense, and likely duration of the litigation; (8) the stage of the proceedings and the amount of discovery so far completed and yet to be done; (9) the risks of establishing liability and damages; (10) the allocations and trade-offs contained within the settlement agreement; (11) the risk of maintaining a class action throughout trial; (12) counsel's negotiations; (13) the reasonableness of attorney fees that will be paid to class counsel, defense counsel, and class members' individual counsel; (14) the reaction of the class members to the proposed settlement; (15) the public interest; and (16) the reasonableness of the settlement fund in light of the best possible recovery and all attendant risks of litigation. See Class Order at 38-50 (discussing these factors).

for Complex Litigation, §30.41, at 236-37 (3rd ed. 1995).

Discussion with counsel reveals the great likelihood that the parties will, in the future, submit new proposed settlement agreements. The parties' continuing discovery and negotiations will surely lead to further reallocations, perhaps changing the apportionment between hip claimants and knee claimants, or between guaranteed fixed compensatory payments and extraordinary injury payments. Even if this Court believes those allocations should be different, it may not, at this juncture, second guess the settlement terms, especially when the Court is satisfied those terms are the product of good-faith, arms-length negotiations of counsel. See Armstrong v. Board of School Directors of City of Milwaukee, 616 F.2d 305, 315 (7th Cir. 1980) ("[j]udges should not substitute their own judgment as to optimal settlement terms for the judgment of the litigants and their counsel"); Officers for Justice, 688 F.2d at 625 ("[t]he proposed settlement is not to be judged against a hypothetical or speculative measure of what might have been achieved by the negotiators"); Duhaime v. John Hancock Mut. Life Ins. Co., 177 F.R.D. 54, 68 (D. Mass. 1997) ("[i]n general, a settlement arrived at after genuine arm's length bargaining may be presumed to be fair"); In re Orthopedic Bone Screw Prods. Liab. Litig., 176 F.R.D. 158, 184 (E.D. Pa. 1997) ("[s]ignificant weight should be attributed 'to the belief of experienced counsel that settlement is in the best interest of the class'") (internal citations omitted). The Court will scrutinize these allocations, and all other terms of the proposed settlement agreement, at the final fairness hearing. It is sufficient here to state that the Court is preliminarily satisfied that the Fourth Settlement Agreement is fair.

B. Sulzer AG.

The Court adds here its observations about the status of Sulzer AG in the context of the fairness of the settlement agreement. It is worth noting that the question of whether and to what extent defendant Sulzer AG will contribute funds to the settlement of this case is not settled. To the contrary, the parties have made clear that this question is central and remains hotly disputed. Plaintiffs' class counsel, in particular, have made it clear that they intend to continue vigorous discovery directed at the question of Sulzer AG's liability in this case.

The Court reiterates here that the extent of Sulzer AG's participation in this settlement by way of providing compensation to the class is one of the factors this Court will examine most closely, at the final fairness hearing. After discovery has concluded, the Court expects to be presented with one of three scenarios: (1) there is extremely strong proof that Sulzer AG cannot be held liable in this case; (2) Sulzer AG has provided substantial compensation in exchange for being released from claims brought by the class; or (3) Sulzer AG is not a part of the settlement and is not released.

The Court's preliminary conclusion that the Fourth Settlement Agreement is fair rests in large part on the knowledge that the parties are working very hard toward more fully resolving the liability of Sulzer AG.

V. Notice

In its Notice Order, the Court earlier applied Fed. R. Civ. P. 23(c)(2) and approved the plan of notice proposed by the parties, with certain modifications. The parties now propose applying the same plan of notice already approved, and the Court agrees.

The parties also submit a proposed preliminary notice, preliminary summary notice, and press release, all of which now purport to give notice to both hip claimants and knee claimants. As before, the Court generally finds these documents appropriate and sufficient, but concludes that certain additions and amendments to these proposed documents will advance the purposes of Rule 23(c)(2). Accordingly, the Court has attached to this Order an amended version of these three documents, and directs the parties to use these amended documents in carrying out their plan for giving preliminary notice to the class.

VI. Conclusion.

With the currently pending motions, the parties seek to include "knee claimants" in this national class action litigation, which heretofore has included only "hip claimants." For the reasons stated, the Court concludes that it is appropriate to do so. Accordingly, the Court grants the motion to amend the complaint to include knee claimants, grants the motion to amend the Class Order to include knee claimants as part of the conditional class, grants the motion for preliminary approval of the amended class action settlement agreement (which now includes knee claimants), and grants the motion to amend the Notice Order to give notice to knee claimants. The Court will rule separately on the defendants' motion to amend the Injunction Order.

VII. Summary.

For ease of reference, the Court recapitulates here the critical language contained in this Order.

- Plaintiffs' motion to file a second amended class action complaint to include a subclass of persons who received certain knee implants is **GRANTED**.

- The caption of this case is hereby changed to "In Re: Sulzer Hip Prosthesis and Knee Prosthesis Liability Litigation."

- Plaintiffs' motion to amend the definition of the class to include knee claimants is **GRANTED**, and the Court conditionally certifies the following class:

> All citizens or residents of the United States who have had Affected Inter-Op acetabular shell hip implants or Affected Natural Knee II tibia1 baseplate implants placed in their bodies, together with their associated consortium claimants.[18] Further, this class shall be divided into four subclasses, as follows: Subclass 1 shall consist of those class members who received Affected Inter-Op hip implants and who undergo revision surgery to correct problems with those implants prior to the Final Judicial Approval Date, and their associated consortium claimants. Subclass 2 shall consist of class members who received Affected Inter-Op hip implants and may need to undergo revision surgery to correct problems with those implants after the Final Judicial Approval Date, and their associated consortium claimants. Subclass 3 shall consist of those class members who received Affected Natural Knee II baseplate implants and who undergo revision surgery to correct problems with those implants prior to the Final Judicial Approval Date, and their associated consortium claimants. Subclass 4 shall consist of class members who received Affected Natural Knee II baseplate implants and may need to undergo revision surgery to correct problems with those implants after the Final Judicial Approval Date, and their associated consortium claimants.[19]

- The Court grants preliminary approval to the amended class action settlement agreement, which includes settlement of claims related to Sulzer knee implants.

- The Court approves the parties' amended proposed plan for giving initial notice of the pendency of a class action, including their proposed forms of notice, with certain minor modifications.

IT IS SO ORDERED.

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[18] The "Affected Inter-Op acetabular shell hip implants" and "Affected Natural Knee II tibia1 baseplate implants" will be identified with particularity by the parties to the proposed settlement agreement.

[19] In this context, the term "Final Judicial Approval Date" means the date (if any) on which this Court's approval of the proposed settlement agreement becomes final by the exhaustion of all appeals.

s/Kathleen M. O'Malley
KATHLEEN McDONALD O'MALLEY
UNITED STATES DISTRICT JUDGE